K030723

APR - 3 2003

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 C. F.R. § 807.92.

Submitted by:	Susan Turner, Ph.D. Director, Regulatory Affairs & Quality Assurance Integrated Vascular Systems, Inc. 743 N. Pastoria Ave. Sunnyvale, CA 94085 Telephone: (408) 328-9090 Fax: (408) 328-9099	
Date prepared:	March 5, 2003	
Device name:	IVS Introducer Set, Model 1003	
Common name:	Catheter introducer, vessel dilator for percutaneous catheterization, catheter guide wire	
Classification names:	**Regulation # and Product Code**	**Classification Name**
	21 C.F.R. § 870.1340 DYB	Catheter introducer
	21 C.F.R. § 870.1310 DYB	Vessel dilator for percutaneous catheterization
	21 C.F.R. § 870.1330 DYB	Catheter guide wire
Predicate devices:	IVS Introducer Set, Model 1001, K020789, K021004, K964814	
Device description:	The IVS Introducer Set consists of a 6 French Introducer Sheath, a Dilator and a 0.38" (0.97mm) 'J' tip Guidewire	
Indication for Use:	The IVS Introducer Set is indicated for use in procedures requiring percutaneous introduction of intravascular devices.	
Technological characteristics:	The Model 1003 Introducer Set has the same technologic characteristics as the Model 1001 (K020879) device.	
Testing:	The IVS Introducer Set has been tested *in vitro* and in clinical model systems. Test results show that the modifications to the device do not affect the safety or effectiveness of the device for the intended use.	

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Integrated Vascular Systems, Inc.
c/o Susan Turner, Ph.D.
743 N. Pastoria Avenue
Sunnyvale, CA 94085

Re: K030723
IVS Introducer Set, Model 1003
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: March 6, 2003
Received: March 7, 2003

Dear Dr. Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known) K030723

Device Name IVS Introducer Set, Model 1003

Indications For Use The IVS Introducer Set is indicated for use in procedures requiring percutaneous introduction of intravascular devices.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) K030723

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR § 801.109)